29 January 2014
EMA/126483/2014

Minutes of the Enpr-EMA Working Groups (WGs) meeting

23 January 2014, 14:00-15:45 UK time by teleconference

Attendees:

Enpr-EMA chair: Mark Turner

Enpr-EMA co-chair: Irmgard Eichler (EMA)

Enpr-EMA secretariat: Benjamin Pelle, Isabel Perez (EMA)

Coordinating Group Members: Anne Junker, Dirk Mentzer, Kalle Hoppu, Evelyne Jacqz-Aigrain, Pirkko Lepola, Saskia de Wilt

Invited participant: Ralf Herold (EMA), Sue Tansey (WG3-5), Allison Needham (WG4), Peter Salabank (WG4), Jo Mendrum (WG4), Saul Faust (WG6), Ron Portman (WG6)

Apologies:

Gilles Vassal, Carlo Giaquinto, Gareth Veal, Tim Lee, Jose Drabwell, David Coghill, Christina Peters, Nicola Rupperto, Andrea Biondi, Adamos Hadjipanayis, Mike Sharland

	Item	Summary of discussion	Action
1	WG 1 (Approaches to priority setting)	No update. The chair of the WG will be requested to provide a short update in writing.	EMA, WG1
2	WG 2 (Broad engagement in priority setting)	No update. The chair of the WG will be requested to provide a short update in writing.	EMA, WG2
3	Merged WG 3-5 (How to establish communication between Enpr-EMA, networks and industry & Sharing good practices within Enpr-EMA and with industry partners)	The first preliminary results of the surveys to Networks and Industry were presented. The EMA will re-advertise the survey with extended deadline to 14 February 2014 Full results of the surveys to be presented at Enpr-EMA annual workshop.	EMA, WG3-5

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8669
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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4	WG 4 (Dialogue and interaction with Ethics Committees)	A list of the problems in attaining ethics approval for multi centered trials across jurisdictions and countries has been compiled together with proposals for short and long-term solutions. Short term proposal: check-list for Ethics Committees to be drafted; submission to sponsors, investigators and national Ethic Committees It is proposed to explore • Involvement of (Global research in paediatrics(GRIP) for potential training/interaction with Ethics Committee once check-list has been created • Involvement of EMA Health Care Professionals Working Party (HCPWP)	WG4
5	WG 6 (A framework for networks to interact with industry and regulators when implementation/conduct of clinical trials agreed in PIPs is no longer possible)	Paper to be drafted on information/standard processes needed for clinical trial feasibility; paper to be sent end of January March: TC with the group to finalise outputs to the paper Same approach to be applied in EU, Canada and USA Potentially to be discussed with FDA	WG6
6	WG 7 (Neonatology)	TC in February with EMA colleagues and PDCO members to decide on joint activities and potentially choose one single topic (clinical trials in neonates) to start with; report to be done at the Enpr-EMA annual workshop Initiatives in the USA: FDA has an advisory group for neonates; at next EMA/FDA monthly TC discussion scheduled to explore potential collaboration.	WG7
7	WG 8 (Paediatric Pharmacovigilance)	Concept Paper on the revision of the guideline on conduct of pharmacovigilance for medicines used by the paediatric population has been drafted with active participation and commenting from members of WG 8; comments from PRAC currently awaited. Concept paper to be adopted at PRAC/PDCO March meetings WG now to focus on other defined objectives of their work plan	WG8
8	WG 9 (Strategies for funding and maintaining a paediatric research network)	Model to be developed to see how much it costs to run and sustain a paediatric clinical trial network and the number of staff it does involve (example of UK MCRN) Feedback needed from other networks with a different organisational structure, once model has been created	WG9

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9	WG 10 (FP7 Projects)	Alan Boddy (chair) has resigned EMA will host a meeting on 30/01/14 with FP7 grant recipients into off-patent medicines in children. It is planned to prepare a presentation to the PDCO about the hurdles/difficulties related to development of off-patent medicines in Europe and to create a roadmap to lobby the European Commission (EC) about the need to support medicines development in children Adriana Ceci to present results of survey on FP7 grant recipients. A few representatives of the WG will be invited to the PDCO to discuss PUMA process (PIP-PDCO) and interactions with EC once the hurdles have been identified and proposals have been made by the WG members.	WG10
10	WG 11 (Strategic approaches to raise awareness of Enpr-EMA and the need to conduct paediatric clinical trials among learned societies)	This working group has not yet been established. Individual networks should promote Enpr-EMA at annual conferences of learned societies by presenting some posters on the work of the networks Progress will be made once WG 3-5 actions have been implemented and best practice examples have been identified	WG11